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EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/915,780

Applicant(s)

TERNG ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 10-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 23-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The applicant's Response filed June 7, 2004 to the Office action mailed December 3, 2003 has been entered. Claims 1-36 are pending. Claims 10-22 have been withdrawn from further consideration for being drawn to a non-elected invention.

1. The rejection of claims 5 and 9 under 35 U.S.C. 112, second paragraph is withdrawn.
2. Claims 1-4, 6-8, 23-26, 30 and 32-36 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Drazen et al. (6,156,503) in view of Ugozzoli et al. (DATA, 1992, Vol. 9(4), pg. 107-112).

Drazen et al. disclose a method and kit of identifying individuals at risk for an adverse response to β -agonist therapy (See column 1, lines 51-54). The method involves using allelic specific primer which has the same structure as the structure of the claimed discrimination primer (See column 11, lines 12-26) except the primer of Drazen et al. does not comprise a binding member covalently bonded to the 5' end of the primer. The primer of Drazen et al. has a mismatch at penultimate position from the 3' end (See column 11, lines 17-26) and a segment of nucleotide located immediately 5' to the second base is complementary to a part of target nucleic acid (the nucleic acid) (See column 11, lines 17-26).

Drazen et al. also disclose a kit to include primer set capable of amplifying and distinguish the allele specific gene (See column 4, lines 25-35).

Drazen et al. do not disclose that the primer comprises a binding member of a specific binding pair covalently bonded to the 5' end of the primer and the binding member is an oligonucleotide which is not complementary to any part of the nucleic acid.

Ugozzoli et al. disclose a method for determining whether a particular nucleic acid sequence is present in a sample. The method applies an allele-specific primer, which has 5' portion complementary to a different preselected nucleic acid sequence (See pg. 107, column 1, the abstract). The 5' portion is an oligonucleotide 6 to 50 nucleotides in length (See pg. 110, fig. 1). And there is an capturing nucleic acid sequence immobilized on the solid support (See pg. 110, fig. 1)

The limitations of claim 1 are interpreted as there is a first binding member of a specific binding pair located at 5' terminus which is the same as the 5' portion of the primer of Ugozzoli et al. (See pg. 107, column 1, the abstract) and a second binding member affixed on a solid substrate which is the same capturing nucleic acid sequence immobilized on the solid support of Ugozzoli et al. (See pg. 110, fig. 1). Therefore, the teachings of Drazen et al. in view of Ugozzoli et al. suggest the limitations of instant claims.

One of ordinary skill in the art would have been motivated to modify the primer of Drazen et al. by applying the 5' portion of the primer of Ugozzoli et al. for making an discrimination primer for amplifying a first base at a position suspected of a polymorphism and a second base immediately 3' to the first base. The motivation is that by using the binding member of a specific binding pair at 5' end of the primer, it allows the primer-extension product to be immobilized on a solid support by hybridization and it makes the method more specific and offers a valid alternative to study DNA polymorphism (See pg. 111, column 2, third paragraph). It would have been prima facie obvious to make the primer having a first binding member included in a specific binding pair located at the 5' portion which is not complementary to any part of the nucleic acid.

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The response filed June 7, 2004 argues that the teachings of Ugozzoli et al. are limited to primer extension and is not applicable to PCR amplification, as required by claim 1. The response further argues that in PCR amplification, the amplification of primers is in an exponential manner, while in primer extension, the primer extension generates single-stranded extension products in a linear manner. However, the claims are drawn to the product, which is an unlabeled discrimination primer. The teachings of Drazen et al. in view of the teachings of Ugozzoli et al. read on the features of the discrimination primers in the limitations of the claims. Thus, the rejection is maintained.

3. The Declaration by Dr. Shin-Hwan Wang under 37 CFR 1.132 filed June 7, 2004 is insufficient to overcome the rejection of claims 1-4, 6-8, 23-26, 30 and 32-36 based upon the teachings of Drazen et al. in view of the teachings of Ugozzoli et al as set forth in the last Office action because: the response argues that the instantly invented discrimination primer has 3' portion of the R11-1-3mis 18 discrimination primer cited as SEQ ID NO: 2. However, this limitation is not cited in claim 1. Thus the Declaration is insufficient to overcome the rejection.

4. Claims 5, 9, 27-29 and 31 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Drazen et al. (6,156,503) in view of Ugozzoli et al. (DATA, 1992, Vol. 9(4), pg. 107-112) as applied to claims 1-4, 6-8, 23-26, 30 and 32-36 above, and further in view of Drmanac et al. (6,383,742, issued May 7, 2002).

The teachings of Drazen et al. and Ugozzoli et al. are set forth in section 2 above. Drazen et al. and Ugozzoli et al. do not disclose the binding member, which is peptide and the primer, is labeled.

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Drmanac et al. disclose a method of detecting a target nucleic acid species involving using labeled probe (See the Abstract). The label can be ligands which can serve as specific binding members to a labeled antibody, chemiluminescers, enzymes, antibodies which can serve as a specific binding pair member for a labeled ligand (See column 18, lines 64-67 to column 19, lines 1-4). The antibodies and enzymes are peptide.

Therefore one of ordinary skill in the art would have been motivated to modify the primer of Drazen et al. by applying the antibody as a binding member as taught by Drmanac et al. (See column 18, lines 64-67 to column 19, lines 1-4 and column 22, lines 1-14) at 5' terminus of the primer. The motivation is that by using the binding member of a specific binding pair at 5' end of the nucleic acid primer, a small number of nucleic acid samples can be fast identified (See column 6, lines 64-67). It would have been prima facie obvious to make the discrimination primer with a peptide-binding member at 5' terminus.

The response argues that the discrimination primer recited in claim 1 and the first primer recited in claims 1 and 23 are unlabeled. However, there is a second primer cited in claim 28, which is labeled at 5' end. This is the reason applying the teachings of Drmanac et al. Thus, the combination of the references renders claims obvious and the rejection is maintained.

NEW GROUND REJECTION NESCESITATED BY THE AMENDMENT

Claim Rejections - 35 USC § 112

5. Claims 1-9 and 23-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention since the newly added limitation “an unlabeled” discrimination primer has no support in the specification. Thus, it constitutes new matter.

Summary

6. No claims are allowable.
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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8. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

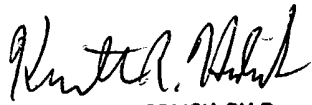
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

August 25, 2004


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
9/2/04